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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BENJAMIN WISE, an individual,

Plaintiff,

vs.

MONTEREY COUNTY HOSPITALITY ASSOCATION HEALTH AND WELFARE PLAN; UNITED HEALTHCARE SERVICES, INC.; MONTEREY COUNTY HOSPITALITY ASSOCIATION; MVI ADMINISTRATORS INSURANCE SOLUTIONS, INC.; MAXIMUS FEDERAL SERVICES, INC.; UNITEDHEALTHCARE INSURANCE COMPANY; AND DOES 1 THROUGH 10.

Defendants.

CASE NO.:

COMPLAINT FOR:
(1) TO RECOVER BENEFITS DUE UNDER ERISA, ENFORCE AND/OR CLARIFY RIGHTS UNDER ERISA, AND ENFORCE THE TERMS OF ERISA, 29 U.S.C. § 1132(a);
(2) VIOLATION OF ERISA § 404; AND
(3) VIOLATION OF ERISA § 503

I. JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, 1332 and 1337, and ERISA § 502(e)(1), 29 U.S.C. § 1132(e)(1), as a result of the denial of benefits that Plaintiff Benjamin Wise is entitled to under an ERISA-governed welfare benefit plan and breaches of fiduciary duties by each of the

Defendants.

2. Venue is proper in this District pursuant to ERISA § 502(e)(2), 29 U.S.C. § 1132(e)(2), because the breaches occurred and caused consequences in this Judicial District. Plaintiff, at all times relevant, was employed by Eric Miller Architects, a "Participating Employer" that has adopted the Plan, in this Judicial District; Plaintiff received the denial of benefits at issue from the Plan in this Judicial District; the Plan is administered in this Judicial District; Defendants regularly conduct business in this Judicial District and the events giving rise to this case took place in this Judicial District as a result of the employment relationship entered into in this Judicial District.

3. This Complaint arises from the denial of benefits and breaches of fiduciary duty by Defendants Monterey County Hospitality Association; Monterey County Hospitality Association Health and Welfare Plan, United HealthCare Services, Inc. and MVI Administrators Insurance Solutions, Inc. (collectively, "Defendants"). Defendants failed to properly administer the Plan that Plaintiff Benjamin Wise ("Benjamin") participates in through his employer, Eric Miller Architects, by improperly denying Benjamin coverage for a myoelectric elbow-wrist-hand orthosis ("EWHO").

4. In 2002, Benjamin was involved in a motor vehicle accident that resulted in the total paralysis of his left arm to above his deltoid. A myoelectric EWHO would return function to his arm and aid with assisted daily living activities for Benjamin, such as lifting, feeding himself and all other basic daily living tasks that require arm function.

5. The MyoPro orthosis manufactured by Myomo, Inc. is the type of device that could restore function to Benjamin's arms to assist him with his living needs at home. The MyoPro has been peer reviewed in numerous articles, it has been approved by numerous health insurance companies and government agencies, and is registered with the Food and Drug Administration ("FDA").

6. Defendants have improperly denied benefits to Benjamin by refusing to pre-authorize and cover the cost of the MyoPro orthosis on the grounds that the device is excluded from coverage because Defendants claim the device is "experimental or investigational" and not a covered expense. Given the widespread acceptance by the medical community, many health insurance companies and medical institutions, Defendants' motivation to deny coverage stems from their desire to reduce costs to the Plan and/or themselves or to benefit themselves.

7. Defendants claim that the device is "experimental and/or investigational" to "treat" upper extremity paralysis. The device is not being prescribed for the purpose of "treating" Benjamin's paralysis per se, but rather to restore function to Benjamin's arm to allow him to have some independence in his daily living activities. Standard or conventional treatments will not restore any function to Benjamin's arm because the paralysis cannot be reversed. The MyoPro is the only device or treatment that can restore any such function. No other treatment or device exists that would restore movement to Benjamin's arm.

II. THE PARTIES

8. Plaintiff Benjamin Wise resides in Pacific Grove, Monterey County, California. Benjamin, at all times relevant, was and is an employee of Eric Miller Architects, a member of Defendant Monterey County Hospitality Association.

9. Defendant Monterey County Hospitality Association Health and Welfare Plan (the "Plan") is a qualified welfare benefit plan subject to ERISA with its principal place of administration located in Monterey, California. According to the Summary Plan Description:

> "The Plan is a welfare benefit plan that provides group health and welfare benefits through a multiple employer welfare arrangement which is funded by a voluntary employees' beneficiary association ("VEBA") trust fund, the Monterey County Hospitality Association Health and Welfare Trust ("Trust"), established under section 501(c)(9) of the Internal Revenue Code. All benefits are fully insured. The Plan is not collectively bargained and does not apply to employees covered by collective bargaining agreements. Contributions are paid by Participating Employers and COBRA beneficiaries to the Trust"

10. Defendant Monterey County Hospitality Association ("MCHA") is a California Corporation with its principal place of business located in Monterey, California. MCHA is the Plan Sponsor for the Plan.

11. The Plan Trustees are designated as the Plan Administrator. However, the Trustees have contracted with a third party, MVI Administrators Insurance Solutions, Inc., to perform many of the Plan Administrator's tasks.

12. Defendant MVI Administrators Insurance Solutions, Inc. ("MVI") is a California corporation with its principal place of business located in San Diego, California. The Plan documents state that any reference to the Plan Administrator therein refers to MVI.

13. Defendant UnitedHealthCare Insurance Company ("UHCIC") is a Connecticut corporation which is principal place of business located in Hartford, Connecticut. UHCIC provides health care services and health insurance plans under the Plan, including PPO (preferred provider organization), H.S.A. (health savings account) and "Select" health insurance plans.

14. Defendant United HealthCare Services, Inc. ("UHC") is a Minnesota corporation with its principal place of business located, Minnetonka, Minnesota. UHC provides health care services and/or handles benefit decisions and appeals thereof on behalf of Defendant UHCIC.

15. Defendant MAXIMUS Federal Services, Inc. ("Maximus") is a Virginia corporation with its principal place of business located in Reston, Virginia. Maximus, among other things, serves an Independent Medical Review Organization and conducts external reviews of benefit denials by health insurance companies and employment benefit plans.

III. GENERAL ALLEGATIONS

A. Benjamin's Injury

16. Benjamin, who is 41 years old, was involved in a motor vehicle accident in 2002. As a result of the accident, he suffered multiple arm and leg

fractures as well as a left brachial plexus injury. He continues to suffer from weakness, numbness and pain in his left arm. The brachial plexus is a network of nerves that extend from the spinal cord through the cervicoaxillary canal in the neck, over the first rib and into the arm pit.

17. Between 2003 and 2005, Benjamin underwent a number of nerve transfers in an attempt to reinnervate his arm. Thereafter, Benjamin received occupational therapy, rehabilitation treatment and static orthoses.

18. Despite efforts to repair and/or rehabilitate Benjamin's arm, his arm is diagnosed as flail distally from the shoulder. A "flail arm" is a medical term that refers to an arm in which the native, primary nerves have been severed. It results in complete lack of mobility and sensation. In addition, the muscles atrophy, and the arm swings loosely at the side like a "dead weight."

B. Benjamin's Current Condition and Daily Challenges

19. Because Benjamin does not have the use of his left arm, he is reliant on his right arm to complete all his daily living tasks. He frequently requires help at home with basic activities, such as dressing, feeding himself, and household chores. His qualify of life and earning potential are impacted by this injury.

20. The loss of the use of his left arm renders Benjamin susceptible to overuse syndrome to his right arm, which can have repercussions to Benjamin's overall health. Because the damage to Benjamin's nerves cannot be reversed, he has lost total use of his left arm and is reliant solely on his right arm. Powered assistance is the only available option for Benjamin to have any type of left arm function. Benjamin has tried all available traditional therapies without success. There is no other option available restore functionality to his arms other than a myoelectric EWHO.

21. On July 5, 2017, Benjamin was seen by Ken Hashimoto, M.D. for an assessment and to discuss a possible referral for a "Myomo prosthetic." Benjamin reported to Dr. Hashimoto that he tried to use the Myomo device and it was able to

detect his nerve activities. Dr. Hashimoto determined that Benjamin "is a candidate for a 'Myomo prosthetic' for his [left] arm . . . we decided to send a [referral] for MyoPro device for his L. arm to: VIPO, Inc."

22. Benjamin was evaluated by certified prosthetist/orthotists at Valley Institute of Prosthetics and Orthotics ("VIPO") in Bakersfield, California. VIPO determined that Benjamin met the criteria to use a myoelectric elbow-wrist-hand orthosis to restore elbow hand function.

C. The Myomo MyoPro Orthosis Restores Use and Function to Impaired Arms

23. Myoelectric orthoses were first created by Reinhold Reiter in Germany in the 1940s. Over the past 50 years, the technology has progressed from single muscle control to "complex muscle group activity control." In the 1990s, the Department of Veterans Affairs ("VA") supported further research because it determined that myoelectric orthoses could benefit veterans who had upper extremity impairment. "In 2006, work in myoelectric upper extremity orthoses at MIT was commercialized resulting in the development of the Myo-Pro myoelectric elbow-wrist-hand orthosis (EWHO)"

24. Myomo, Inc. describes its myoelectric EWHO, the MyoPro, as follows:

> "MyoPro is a powered orthosis (brace) designed to help restore function to arms and hands paralyzed or weakened by CVA stroke, brachial plexus injury, cerebral palsy or other neurological or neuromuscular disease or injury.
>
> MyoPro is a breakthrough in modern medical robotics. Originally developed at MIT with Harvard Medical School, it works by reading the faint nerve signals (myoelectric signals) from the surface of the skin (no implants) then activating small motors to move the arm and hand as the user intends (no electrical stimulation). The user is completely controlling their own hand and arm; the brace amplifies their weak muscle signal to help move the limb. It has been called 'power steering for your arm'."
>
> "While there are many prosthetic products for those who have lost their arms, hands or legs, and while there are orthotic products to support weak legs, MyoPro is the only product on the market to help restore function for those who still have their arms and hands but are unable to use them."

> The MyoPro may alleviate paralysis and allow a user to experience movement in the time it takes to put it on. It is the only device available that can immediately enable use of a paralyzed hand and arm. With the MyoPro, everyday tasks such as feeding and dressing may now be done again, everyday."

25. According to Myomo's CEO, "[i]t is the only device that, sensing a patient's own neurological signals through non-invasive sensors on the arm, can restore their ability to use their arms and hands so that they can return to work, live independently and reduce their cost of care."

26. The MyoPro is registered with the FDA as a class II medical device. It is "510(k) exempt" under the Food, Drug and Cosmetic Act from marketing clearance because of its low risk and proven safety. A 510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is at least as safe and effective as a legally marketed device (21 CFR § 807.92(a)(3)) that is not subject to premarket authorization. As a result, the MyoPro does not require FDA approval to be marketed. Myomo is compliant with FDA good engineering practices, is routinely recertified/audited by the FDA (most recently in 2018) and other independent bodies using international standards (ISO13485, MDSAP). Myomo has also obtained a CE Mark and a Canadian Medical Device license because of its high standards.

D. Acceptance of the MyoPro By Health Insurance Plans and Medical Institutions

27. There has been wide acceptance of myoelectric EWHOs in the medical community. The MyoPro, such as the one that Benjamin seeks coverage for, has been approved by health insurance companies throughout the United States. For example, the MyoPro has been approved for coverage by the Blue Cross Blue Shield Association in the states of California, Colorado, Connecticut, Florida, Illinois, Indiana, Massachusetts, Michigan, Minnesota, New Jersey, New York, North Carolina, Ohio, South Carolina and Texas. Numerous other health insurance

companies have approved the MyoPro[1]

28. In some cases, insureds have gone through the appeal process when a health insurance company and/or employee benefit plan has denied coverage for the MyoPro device and the insured prevailed. Insureds have prevailed in appeals against United Healthcare, Anthem and Medical Mutual, among others.

29. Medicaid plans in the states of California, Connecticut, Maine, New York and Pennsylvania have approved coverage for the MyoPro.

30. Numerous hospitals and medical institutions have accepted and used the MyoPro in their treatment of upper extremity impairment, including the Mayo Clinic, Johns Hopkins, Cleveland Clinic, Hospital for Special Surgery and the VA.

31. The determination by the above-referenced insurance companies, government agencies and medical institutions to cover and utilize the MyoPro and approve it as an accepted treatment for upper extremity impairment evidences that the MyoPro is neither experimental nor investigational. The safety, efficacy and effectiveness of myoelectric orthoses and prostheses have been provided through the more than fifty years of medical literature, studies and peer-reviews of the devices. One study found that "[m]yoelectric elbow-wrist-hand orthosis use significantly reduces UE [upper extremity] impairment and increases performance of certain functional tasks in chronic, moderately impaired stroke."[2]

32. Another article noted that "higher treatment intensity achieved using robot-assisted therapy is the most likely explanation for the enhanced results recorded in the upper extremities."[3]

33. A study of another Myomo orthosis, which was replaced by the

[1] Among the health insurance companies that have covered the MyoPro are the following: Ascension, Aetna, Affinity, Ameriben, Amerigroup, Anthem, Carelink, Cigna, CoreSource, Emblem, Florida Hospital Care Advantage, Harvard Pilgrim, Humana, IEHP, Kaiser Permanente, Medical Mutual of Ohio, Neighborhood Health, Preferred One, Qualchoice, Tricare, Tufts, Unity, United Healthcare, Unity Health Insurance and the VA.

[2] Peters HT, Page SJ, Persch A. Giving Them a Hand: Wearing a Myoelectric Elbow-Wrist-Hand Orthosis Reduces Upper Extremity Impairment in Chronic Stroke. Arch Phys Med Rehabil. 2017 Jan 24.

[3] Waldner A, Tomelleri C, Hesse S. Transfer of scientific concepts to clinical practice: recent robotassisted training studies. Funct Neurol. 2009 Oct-Dec;24(4):173-7.

MyoPro, noted that "[t]he study results support our hypothesis that a combined clinic-home robotic program integrating the affected arm into functional activities is feasible and a potentially effective therapeutic approach. . . . Participants demonstrated statistically significant improvements in both arm impairment and self-reported use of the arm from baseline to discharge; they continued to report significant improvement in actual use of the arm at 3-month follow-up."[4]

E. The Monterey County Hospitality Association Health and Welfare Plan

34. The Plan, sponsored by MCHA, effective August 1, 2017, is a group health and welfare Plan created for the exclusive benefit of its employees and their eligible dependents.

35. Benefits of the Plan are provided by insurance providers who contract with the Trust, "and are subject to the provisions of the Plan, the Trust Agreement, [the] employer's Adoption Agreement, and the determination of the Plan Administrator or health insurance issuer(s)."

36. On September 26, 2017, Benjamin's employer, Eric Miller Architects, adopted the Plan and became a Participating Employer of the Plan.

37. In the Summary Plan Description of the Plan, under the heading "Benefit Claims and Appeals," it states the following:

> "Procedures for submitting claims and appeals to obtain benefits are outlined in the insurance carrier's evidences of coverage or other benefits information materials, which are available without charge by contacting the Plan Administrator.
>
> Insurance carriers shall have full discretionary authority to decide all claims and appeals for benefits under the Plan, and such determinations shall be final and binding upon all parties thereto, subject only to judicial review. No action in court may be brought to enforce any right under the Plan until a claim therefore has been submitted to and determined by the insurance carriers and the carriers' appeal procedure has been exhausted. Thereafter, the only action which may be brought is one to enforce the decision of the insurance carrier or to clarify the rights of the claimant under such decision. Any such action must be filed within 12 months of the insurance carrier's final appeal denial or,

[4] Kim GJ, Rivera L, Stein J. Combined Clinic-Home Approach for Upper Limb Robotic Therapy After Stroke: A Pilot Study. Arch Phys Med Rehabil. 2015 Dec;96(12):2243-8.

if later, within three (3) years of the date that the claim is incurred.

38. The Plan offers various health insurance plan options through UHCIC and/or UHC, including PPO and HSA plans. UHCIC and/or UHC sets policies and guidelines regarding coverage of health benefits.

39. Defendant UHC handles benefit determinations and internal appeals of any benefit denials by the Plan, UHC or UHCIC.

F. Benjamin Exhausted All Known Internal and External Appeals Procedures

40. After Benjamin was seen by VIPO, Inc. and recommended for fitment of a myoelectric EWHO, Dr. Brandon Green prepared a History and Physical Exam Review of Benjamin and his condition on or about September 19, 2017. Dr. Green opined that a myoelectric orthosis is the best available technology to help Benjamin provide function to his left arm:

> Since his injury, Mr. Wise has fully exhausted the potential benefits of traditional rehabilitation and less sophisticated medical devices. His experience with static bracing is consistent with the known literature, which shows total lack of functional benefit with traditional upper extremity orthoses. Simply put, no other less costly treatment options remain for Benjamin Wise. Given the severity and chronicity of his left arm weakness, nothing short of an external power actuated orthosis for permanent daily use can be expected to functionally restore this arm. A myoelectric brace is the only viable option for Mr. Wise, and he satisfies all the standard orthotic criteria in most major health plans for the provision of such a device. Specifically, such a device is being prescribed by a qualified provider for the medical purposes of therapeutic support, protection, and restoration of his impaired left arm, it is not useful for a non-injured person, it is to be used in the home, does not serve for mere comfort or convenience, and has been FDA registered with marketing approval since 2012 (registration number: 30006240003).

41. Dr. Green's History and Physical Exam Review served as the basis for Benjamin's initial request for preauthorization coverage of the MyoPro made to UHC.

42. In a letter dated October 10, 2017, UHC denied Benjamin's request for coverage. Tanu Pandey, MD MPH, Medical Director for UHC stated:

> "Based on the information submitted, your health benefit plan and our Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies, and Repairs/Replacements, UnitedHealthcare Policy Version: CDG.009.09 Effective: 10/01/2017; Medical Policy: Prosthetic Devices, Wigs, Specialized, Microprocessor Or Myoelectric Limbs Guideline Number: CDG.018.05 Effective Date: February 1, 2017 guideline, we determined that the health care services are not covered.
>
> Our clinical staff reviewed the case, and the services are not eligible expenses under your plan.
>
> This decision is based on the following plan language found in the Certificate of Coverage in the section entitled -Durable Medical Equipment:
>
> If more than one piece of Durable Medical Equipment can meet your functional needs, Benefits are available only for the equipment that meets the minimum specifications for your needs.
>
> Here is the specific clinical reason for our decision: We have received a request for a new artificial arm for you. You had an injury to the nerves of the arm. We reviewed the information received. We reviewed your benefit plan's document. We reviewed your health plan's medical policy for artificial limbs. This request does not meet your health plan's coverage criteria. The code submitted is incorrect and a more specific code should be provided. Your health plan covers only the most cost effective equipment to meet your needs. This request may not be the most cost effective one. Thus this request is not covered under your health plan.

43. While the letter informed Benjamin of his options for appeal of the decision, it did not inform Benjamin of the statute of limitations with regard to the time limit to bring a court action to recover benefits.

44. On November 22, 2017, Dr. Green submitted an appeal of UHC's denial of benefits to UHC's Appeals Unit. Dr. Green sought to rebut the various rationale used by UHC to deny preauthorization of the MyoPro. Dr. Green demonstrated that the cited UHC policy on medical policy on prosthetics (CDG.018.05) was irrelevant because it governed prosthetic technology and persons with amputations. Benjamin's request was for an orthotic, not a prosthetic because Benjamin is not an amputee. UHC disregarded or did not understand the type of device being requested.

45. Dr. Green also addressed the UHC policy on Durable Medical Equipment (CDG.009.09), which sets forth four criteria to be considered a Covered Health Service. Dr. Green demonstrated that it met the criteria because:

> 1) the device is being ordered by Wise's physician for permanent home use, 2) for the medical purpose of stabilizing and restoring function to his otherwise weak left arm that has failed other surgical and therapeutic measures, 3) the device is a durable, custom fabricated, arm orthosis that is not consumable/disposable, and 4) it is not useful to a person in the absence of disease or disability (it does not enhance normal function). Moreover this orthosis is not excluded by any of the specific clauses in this policy under Coverage Limitations and Exclusions – for instance, there is no other piece of Durable Medical Equipment (cost effective or otherwise) which can meet Mr. Wise's needs, as demonstrated already by the failure of static orthoses.

46. Dr. Green also explained that L3999 was the correct medical code to bill for a custom fabricated orthosis. He pointed to the fact that the U.S. Department of Veterans Affairs (the "VA") has explicitly issued a directive that code L3999 be used for the MyoPro. Likewise, a Medicare directive requires that orthotic joints used to provide assistive motion, such as the Myopro, be coded with L3999.

47. Along with a letter explaining the basis for Benjamin's need for the MyoPro, Dr. Green included (1) a release of medical records and designation to allow Dr. Green to represent Benjamin, (2) the History and Physical Exam Review dated September 19, 2017 prepared by Dr. Green, (3) UHC's letter dated October 10, 2017, initially denying coverage for the MyoPro, (4) UHC's coverage guidelines, (5) Noridian Administrative Services, LLC memo regarding correct coding for orthotic joints, and (6) VA code recommendation for MyoPro.

48. On December 11, 2017, UHC denied Benjamin's appeal. In the letter, UHC provided an incoherent and unsupported denial of Benjamin's appeal. The letter merely copied and pasted various language in UHC's plan language and concluded, without any explanation, that the MyoPro has not been shown to help Benjamin's condition:

> "Based on our review, according to your Benefit Plan, under the Section 'Covered Health Services', Subsection 'Benefits for Covered Health Services', it says:

Benefits are available only if all of the following are true:

- The health care service, supply or Pharmaceutical Product is only a Covered Health Service if it is Medically Necessary. (See definitions of Medically Necessary and Covered Health Service in Section 9: Defined Terms.) . . .

* * *

Based on our review, according to your Benefit Plan, under the Section, 'Covered Health Services', Subsection 'Durable Medical Equipment', it says:

Durable Medical Equipment that meets each of the following criteria:

- Ordered or provided by a Physician for outpatient use primarily in a home setting.
- Used for medical purposes.
- Not consumable or disposable except as needed for the effective use of covered Durable Medical Equipment.
- Not of use to a person in the absence of disease or disability.

Based on our review, according to your Benefit Plan, under the Section 'Exclusions and Limitations', Subsection 'Experimental or Investigational or Unproven Services', it says:

Experimental or Investigational and Unproven Services and all services related to Experimental or Investigational and Unproven Services are excluded except Benefits provided for clinical trials for cancer and for Experimental or Investigational Services and Unproven Services as defined under Section 9: Defined Terms . . .

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Based on our review, according to your Benefit Plan, under the Section 'Exclusions and Limitations', Subsection 'All Other Exclusions', it says:

Health services and supplies that do not meet the definition of a Covered Health Service - see the definition in Section 9: Defined Terms. Covered Health Services are those health services, including services, supplies, or Pharmaceutical Products, which we determine to be all of the following:

- Medically Necessary.
- Not otherwise excluded in this Certificate under Section 2: Exclusions and Limitations.

Based on our review, according to your Benefit Plan, under the Section 'Defined Terms', Subsection 'Covered Health Service(s)', it says:

Those health services, including services, supplies, or Pharmaceutical Products, which we determine to be all of the following:

- Medically Necessary.
- Described as a Covered Health Service in this Certificate under Section 1: Covered Health Services and in the Schedule of Benefits.
- Not otherwise excluded in this Certificate under Section 2: Exclusions and Limitations.

Based on our review, according to your Benefit Plan, under the Section 'Defined Terms', Subsection 'Durable Medical Equipment', it says:

Medical equipment that is all of the following:

- Can withstand repeated use.
- Is not disposable.
- Is used to serve a medical purpose with respect to treatment of a Sickness, Injury or their symptoms.
- Is generally not useful to a person in the absence of a Sickness, Injury or their symptoms.
- Is appropriate for use, and is primarily used, within the home.
- Is not implantable within the body.

Based on our review, according to your Benefit Plan, under the Section 'Defined Terms', Subsection 'Medically Necessary', it says:

Health care services provided for the purpose of preventing, evaluating, diagnosing or treating a health condition, Mental Illness, substance-related and addictive disorders, condition, disease or its symptoms, that are all of the following.

- In accordance with Generally Accepted Standards of Medical Practice.

- Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for your Sickness, Injury, Mental Illness, substance-related and addictive disorders, disease or its symptoms.
- Not mainly for your convenience or that of your doctor or other health care provider.
- Not more costly than an alternative drug, service(s) or supply that is at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of your Sickness, Injury, disease or symptoms.

* * *

We develop and maintain clinical policies that describe the Generally Accepted Standards of Medical Practice scientific evidence, prevailing medical standards and clinical guidelines supporting our determinations regarding specific services.

* * *

Based on our review, according to your Benefit Plan, under the Section 'Defined Terms', Subsection 'Unproven Service(s)', it says:

Services, including medications, that are determined not to be effective for treatment of the medical condition and/or not to have a beneficial effect on health outcomes due to insufficient and inadequate clinical evidence from well-conducted randomized controlled trials or cohort studies in the prevailing published peer-reviewed medical literature.

- Well-conducted randomized controlled trials. (Two or more treatments are compared to each other, and the patient is not allowed to choose which treatment is received.)
- Well-conducted cohort studies from more than one institution. (Patients who receive study treatment are compared to a group of patients who receive standard therapy. The comparison group must be nearly identical to the study treatment group.)

***

We may consider an otherwise Unproven Service to be a Covered Health Service for a Covered Person with a health condition that is not a Life-Threatening or seriously debilitating condition. For that to occur, all of the following conditions must be met:

- If the service is one that requires review by the U.S. Food and Drug Administration (FDA), it must be FDA-approved.

- It must be performed by a Physician and in a facility with demonstrated experience and expertise.
- The Covered Person must consent to the procedure acknowledging that we do not believe that sufficient clinical evidence has been published in peer-reviewed medical literature to conclude that the service is safe and/or effective.
- At least two studies from more than one institution must be available in published peer-reviewed medical literature that would allow us to conclude that the service is promising but unproven.
- The service must be available from a Network Physician and/or a Network facility.

***

The determination is as follows:

The request to cover a device (MYOPRO) for you was reviewed. We looked at the notes sent to us. We looked at your health plan benefits. The notes show that you have arm weakness (brachial plexopathy). The requested device has not been shown to help your condition. It cannot be covered. The denial is upheld.

Our decision to deny coverage for this service(s) is therefore unchanged.

49. The conclusion that Benjamin merely has arm weakness and the MyoPro will not help his condition is belied by the information and documentation that was presented and supported by several physicians and specialists. Benjamin has a paralyzed arm and not simply arm weakness. The MyoPro is the only device or treatment that can restore use of Benjamin's left arm.

50. UHC advised that he had exhausted the internal appeal process and that Benjamin had the right to request an Independent Medical Review through the California Department of Insurance.

51. Nowhere in UHC's response did it ever address the points and issues raised by Dr. Green. Instead, UHC produced a generic response to avoid being exposed for failing to provide a reasoned response supported by documentation or scientific evidence.

52. Shortly thereafter, Benjamin filed a request for an Independent Medical Review ("IMR") with the California Department of Insurance. In a letter dated January 3, 2018, the California Department of Insurance acknowledged receipt of Benjamin's request for an IMR and stated that he would be notified if his application qualified for an IMR.

53. On January 17, 2018, Dr. Hashimoto completed and executed a Physician Certification Experimental/Investigational Denials required by the California Department of Insurance to facilitate an IMR.

54. In a letter dated January 26, 2018, Dr. Green, on behalf of Benjamin, submitted information and documentation in support of the IMR application, including all prior appeal records and authorization requests, UHC guidelines, UHC coding information, a research study concerning Myoelectric EWHO, a California Department of Managed care external review of Anthem Blue Cross policy against myoelectric upper extremity orthosis, a California Department of Insurance Independent Medical Review of UHC policy against myoelectric upper extremity orthosis and a UHC Coverage Summary regarding experimental procedures and items.

55. In his letter, Dr. Green recited the nature of Benjamin's injury, the failure of standard or traditional forms of treatment and rehabilitation. Dr. Green explained that Benjamin has been recommended for "a custom myoelectric elbow-wrist-hand orthosis (EWHO, the Myopro) for permanent, home use which would immediately replace his lost elbow and hand function."

56. Dr. Green also commented on the literature and trials that have been performed regarding myoelectric EWHOs:

> "It is worth noting that the body of evidence I cited at the outset of this case aggregates original data from over 90 articles, written at dozens of institutions, published in various highly esteemed journals of PM&R, neurology, and medical technology (e.g. Archives of Physical Medicine and Rehabilitation, Cochran Review, The Lancet) with observations of over 1400 patients mostly in randomized, controlled trials – all with varying degrees of upper extremity weakness resulting from neurological damage and all benefitting in demonstrable, causal ways

from powered orthoses."

57. Dr. Green addressed the various erroneous positions taken by UHC in its initial denial of Benjamin's claim and his appeal. For example, Dr. Green again pointed out that UHC wrongly referred to its policy on prosthetics when the MyoPro is an orthosis and not a prosthetic, which is used for amputees.

58. Dr. Green provided two rulings by the California Department of Insurance and the California Department of Managed Health Care in connection with Independent Medical Reviews that overturned previous denials of coverage for the MyoPro. The reviewers involved in those rulings concluded that there are: (1) "multiple published studies supporting the use of myoelectric orthosis technology," (2) "[t]he medical literature supports the superior efficacy of the requested equipment in this clinical setting," and (3) multiple studies prove "the benefit of myoelectric orthoses for a plegic upper extremity" One independent medical reviewer concluded that the MyoPro "is likely to be more beneficial than any available standard therapy."

59. Dr. Green also pointed out that the MyoPro would qualify for an "Investigational Device Exemption under Category B as defined in UHC's own Investigational Devices Policy K (E-003), because this device is known to be safe and effective and has FDA clearance (registration #: 3006240003)."

60. The IMR was conducted through MAXIMUS by three physicians purportedly trained in physical medicine and rehabilitation. None of the physicians state whether they have any experience with the MyoPro or similar devices, nor do they state what experience they have working with someone with the same type of injury as Benjamin. Rather, they each provide identical information regarding their background and training that is vague and generic. Not surprisingly, each of them concluded that "the requested device is not likely to be more beneficial for treatment of the patient's medical condition than any available standard therapy." Yet, none of the physicians state what available standard therapy would compare to the MyoPro or what standard therapy any of them are referring to would be as good as

the MyoPro.

61. Like UHC, none of the physicians address any of the issues raised by Dr. Green in his letter supporting the IMR. Nor do they discuss the bases that UHC relied on to support its denial. Instead, the physicians make generic statements. Two of the physicians claim that the MyoPro is "heavy, bulky, difficult to wear, and difficult to use on a practical basis." Neither physician states that they have any real-world experience using the MyoPro or that they have even seen one in person to form such an opinion of a device that barely weighs three pounds.

62. The tone and lack of detailed information in the reports by the three physicians hired by Maximus demonstrates that Maximus ensures that the physicians provide a generic response that intentionally fails to address any of the issues or points made by Benjamin or his care team and merely serves as a rubber stamp of Defendants' prior decisions.

63. Benjamin made numerous requests and appeals demanding that Defendants reverse their previous benefit denials, promptly pay the previously submitted claim for the MyoPro orthosis and conform its medical policies and claims systems programming so that Defendants' recognize their obligation to pay for the MyoPro and similar orthoses as a covered benefit.

64. As of the date of this Complaint, Defendants have failed to comply in full with these demands.

65. This action is timely commenced within twelve months from the date Benjamin was notified by Defendants that it was finally rejecting Benjamin's claim for coverage of a myoelectric EHWO and that he could no longer appeal Defendants' denial.

IV. CAUSES OF ACTION

COUNT ONE

(Claim for ERISA Benefits)

66. Benjamin incorporates by reference the allegations of paragraphs 1

through 65 as if set forth at length herein.

67. Benjamin files this action pursuant to ERISA §502(a)(1)(B), 28 U.S.C. §1132, to recover benefits due him as a beneficiary of an ERISA plan.

68. As a participant in the Plan, Benjamin is entitled to recover benefits due him and enforce his rights under the terms of the Plan.

69. The Plan requires benefit coverage of medical expenses incurred by Benjamin at usual, customary, and reasonable rates.

70. Defendants are obligated to approve and pay for medically necessary services, covered services, or covered benefits as defined under the Plan. As a participant in the Plan, Benjamin is entitled to coverage of benefits under the ERISA-governed Plan for a myoelectric EHWO because the Plan covers expenses for Durable Medical Equipment such as the MyoPro.

71. Defendants have breached the terms of the Plan by refusing to pre-certify charges covered by the Plan, in violation of ERISA 502(a)(1)(B), 29 U.S.C. § 1132(a)(1)(B).

72. As a result of, among other acts, Defendants' numerous procedural and substantive violations of ERISA, any appeals are deemed exhausted or excused, and Benjamin is entitled to have this Court undertake a de novo review of the issues raised herein. In addition, California Insurance Code § 10110.6(a) bans discretionary clauses in certain insurance policies, including health insurance policies rendering them void. Thus, to the extent the Plan retains discretionary authority to determine whether benefits will be paid, such discretion is prohibited under California law.

73. Moreover, pursuant to 29 U.S.C. § 1132(a)(1)(B), Benjamin is entitled to coverage of the Myomo MyoPro and reimbursement for the costs of the device as provided by the terms of the Plan. Benjamin is also entitled to declaratory and injunctive relief to enforce the terms of the Plans and to clarify his right to future benefits under such plan, as well as attorneys' fees.

COUNT TWO

(Violation of Fiduciary Duties of Loyalty and Due Care in Violation of ERISA)

74. Benjamin incorporates by reference the allegations of paragraphs 1 through 65 as if set forth at length herein.

75. 29 U.S.C. § 1132(a)(3) states that a civil action may be brought by a "participant, beneficiary, or fiduciary to (A) enjoin any act or practice which violates any provision of this subchapter or the terms of the plan, or (B) to obtain other appropriate equitable relief (i) to redress such violations or (ii) to enforce any provisions of this subchapter or the terms of the plan."

76. UHC, MHPA, UCHIC, Maximus and MVI are fiduciaries under ERISA because the Plan is issued pursuant to an employee benefit plan and UHC, MHPA, UCHIC, Maximus and MVI all exercise discretionary authority or discretionary control respecting the management of an employment benefit plan and the disposition of its assets; and have discretionary authority in the administration of the Plan.

77. As ERISA fiduciaries, UHC, MHPA, UCHIC, Maximus and MVI owed Benjamin a duty of care, defined as an obligation to act prudently, with the care, skill, prudence and diligence that a prudent fiduciary would use in the conduct of an enterprise of like character. Further, as fiduciaries, UHC, MHPA, UCHIC, Maximus and MVI were required to ensure that they were acting in accordance with the documents and instruments governing the Plan and in accordance with ERISA § 404(a)(l)(B) and (D), 29 U.S.C. § 1104(a)(l)(B) and (D). In failing to act prudently, and in failing to act in accordance with the documents governing the Plan, UHC, MHPA, UCHIC, Maximus and MVI have violated their fiduciary duty of care.

78. MVI and MHPA as the Plan Administrator and Plan Sponsor, respectively, had a duty to properly oversee the conduct of UHC and UHCIC to ensure that they carried out their fiduciary duties pursuant to the terms of the Plan,

which duty MVI and MHPA failed to carry out, by among other things, failing to ensure that UHC followed all required procedures during the appeal process, failing to ensure that UHC provide a full and fair review, and failing to ensure that UHC and UCHIC followed their own guidelines when evaluating whether the MyoPro qualifies as "Covered Health Services," which it did not.

79. As fiduciaries, UHC, MHPA, UCHIC, Maximus and MVI also owed Benjamin a duty of loyalty, defined as an obligation to make decisions in the interest of its beneficiaries, and to avoid self-dealing or financial arrangements that benefit the fiduciary at the expense of members, in accordance with ERISA § 404(a)(l)(A), 29 U.S.C. § 1104(a)(l)(A) and ERISA § 406, 29 U.S.C. § 1106. Thus, UHC, MHPA, UCHIC, Maximus and MVI could not make benefit determinations for the purpose of saving the Plan, UHC, MHPA, UCHIC, Maximus and/or MVI money, or benefit themselves at the expense of the Plan's participants and beneficiaries. Furthermore, Maximus had an obligation to ensure the physicians its hires have proper expertise and understanding with regard to myoelectric EWHO to ensure that a proper, competent evaluation was conducted, which evaluation did not meet minimum standards.

80. UHC, MHPA, UCHIC, Maximus and MVI have violated their fiduciary duty of loyalty to Benjamin by, among other things, refusing to cover the Myomo MyoPro, to their own advantage, at the expense of the Plan's participants and beneficiaries.

81. Benjamin is entitled to relief to remedy UHC, MHPA, UCHIC, Maximus and MVI's violation of their fiduciary duties under ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), including declaratory, injunctive relief and attorneys' fees.

COUNT THREE

(Denial of Full and Fair Review in Violation of ERISA § 503)

82. Benjamin incorporates by reference the allegations of paragraphs 1 through 65 if set forth at length herein.

83. As a beneficiary of the Plan, Benjamin is entitled to receive protection under ERISA, including (a) a "full and fair review" of all claims denied by Defendants; and (b) compliance by Defendants with applicable claims procedure regulations.

84. Although Defendants are obligated to provide a "full and fair review" of denied claims pursuant to ERISA § 503, 29 U.S.C. § 1133 and applicable regulations, including 29 C.F.R. § 2560.503-1 and 29 C.F.R. § 2590.715-2719, Defendants have failed to do so by, among other actions: refusing to provide the specific reason or reasons for the denial Benjamin's claim; refusing to provide the specific rule, guideline or protocol relied upon in making the decision to deny Benjamin's claim; refusing to describe any additional material or information necessary to perfect a claim, such as the appropriate diagnosis/treatment code; failing to respond to points and issues raised by Benjamin during his appeal; failing to notify Benjamin of his right to judicial review of Defendants' denial of his claim and the time limit for bringing such a claim. By failing to comply with the ERISA claims procedures regulations, Defendants failed to provide a reasonable claims procedure.

85. Because Defendants have failed to comply with the substantive and procedural requirements of ERISA, any administrative remedies are deemed exhausted pursuant to 29 C.F.R. § 2560.503-1(l) and 29 C.F.R. § 2590.715-2719(b)(2)(ii)(F)(1). Finally, exhaustion would be futile because Defendants have adopted a clear policy of excluding coverage for the MyoPro.

86. Benjamin has been harmed by Defendants' failure to provide a full and fair review of appeals submitted under ERISA § 503, 29 U.S.C. § 1133, by Defendants' failures to disclose information relevant to appeals and to comply with applicable claims procedure regulations.

87. Benjamin is entitled to relief under ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), including declaratory and injunctive relief, to remedy Defendants'

failures to provide a full and fair review, to disclose information relevant to appeals, and to comply with applicable claims procedure regulations.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Benjamin Wise respectfully requests that this Court grant the following relief:

A. Declaring that Defendants have breached the terms of the Plan and awarding payment for unpaid benefits, as well as awarding injunctive and declaratory relief to prevent Defendants' continuing actions detailed herein that are unauthorized by the Plan;

B. Declaring that Defendants failed to provide a "full and fair review" under § 503 of ERISA, 29 U.S.C. § 1133, and applicable claims procedure regulations, as well as awarding injunctive, declaratory and other equitable relief to ensure compliance with ERISA and its claims procedure regulations;

C. Declaring that Defendants violated their fiduciary duties under § 404 of ERISA, 29 U.S.C. § 1106, and awarding injunctive, declaratory and other equitable relief to ensure compliance with ERISA;

D. Temporarily and permanently enjoining Defendants from continuing to pursue their actions detailed herein, and ordering Defendants to pay benefits in accordance with the terms of the Plan and applicable law;

E. Awarding restitution for reimbursements improperly withheld by Defendants;

F. Declaring that Defendants have violated the terms of the Plan and/or policies of insurance covering Plaintiff Benjamin Wise;

G. Requiring Defendants to make full payment on all previously denied claims relating to Plaintiff Benjamin Wise's request for coverage of a myoelectric EHWO;

H. Requiring Defendants to pay Plaintiff Benjamin Wise the benefit amounts as required under the Plan;

I. Awarding reasonable attorneys' fees, as provided by common law, federal or state statute, or equity, including Section 502(g) of ERISA, 29 U.S.C. § 1132(g);

J. Awarding costs of suit;

K. Awarding pre-judgment and post-judgment interest as provided by common law, federal or state statute or rule, or equity; and

L. Awarding all other relief that the Court may deem just and proper.

Respectfully submitted,

DATED: December 11, 2018

DAVIS LAW GROUP, PLC

By: /s/ D. Jason Davis
D. Jason Davis
Attorneys for Plaintiff,